REMARKS

Applicants note that the Examiner has verified entry of the amendment filed on November 5, 2002.

Patentability Under 35 USC § 102

Claims 21-32 and 39 are rejected under 35 U.S.C. lO2(b) as allegedly anticipated by Heaton et al. (1995) of record. The Examiner cites Heaton et al. for allegedly disclosing an aqueous nasal spray apomorphine preparation. The Examiner further asserts that "Applicants' claimed limitation of a formulation for enhanced nasal delivery which yields enhanced nasal absorption of apomorphine compound to produce a therapeutic result in a subject within certain amount of time would be an inherent property of the well known apomorphine nasal preparation as taught by the above reference."

Applicants respectfully traverse the stated grounds for rejection and submit that the disclosure of Heaton et al. fails to teach or suggest the subject matter of the claims as amended herein.

The Examiner cites In re Spada, 911 F.2d 705,708, 15 USPQ2d 1655, 1657 (Fed. Ir. 1990) for the asserted proposition that "discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known compositions". Applicants respectfully submit that the asserted holding in this case is inapposite to a determination that the Heaton et al. reference anticipates the subject matter of the instant claims.

Notably, Heaton et al. is cited as allegedly anticipating the subject matter of Applicants' invention. In contrast to the standard for obviousness, an alleged anticipatory reference must disclose all of the elements and limitations of the claimed invention.

> The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. . . .[I]t is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference.

Ex Parte Levy, 17 USPQ2d, 1461, 1462 (Bd.Pat.App.Int. 1990) (citations omitted).

Equally important to the Office's review, a reference that is relied upon as an allegedly anticipatory reference must fulfill all of requirements of 35 U.S.C. § 112, including the requirement for a fully enabling disclosure.

> The standard for anticipation by patenting is the same one of a full enabling disclosure that applies to printed publications, i.e., it must disclose the invention in such full, clear and exact terms as to enable any person skilled in the art to which the invention relates to practice it.

Electronucleonics Laboratories, Inc. et al. v. Abbot Laboratories, 214 USPQ 139, 147 (N.D. Ill. 1981) (underscore added, citations omitted).

As further explained by the Federal Circuit in In re Donohue, 226 USPQ 619, 621 (Fed. Cir. 1985):

> It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it.

In the instant case, the Heaton et al. clearly fail to enable the claimed aqueous apomorphine formulations that yield "enhanced nasal absorption . . . to produce a therapeutic result in a subject" (in accordance with the recited pharmacokinetic values) "without unacceptable adverse side effects in said subject."

On the contrary, Heaton et al. is directed primarily to a sublingual tablet formulation of apomorphine. Although the reference purportedly discloses aqueous apomorphine formulations, the express disclosure of the reference clearly evinces a failure to enable the claimed aqueous formulations having the recited properties. Rather, the reference discloses (in Abstract cited by Examiner) that "aqueous forms (of apomorphine) did not produce useful responses free of side effects." Further evidence of that the Heaton et al. disclosure is nonenabling for Applicants' novel technology is provided at page 203, left column, as follows. From "Study 1", involving sublingual administration of 10 mg and 20 mg "unmodified" liquid apomorphine, the following report is provided:

> Adverse effects were reported at both doses. Eight subjects developed the typical side effects of unmodified apomorphine administration; sudden nausea (and in one instance vomiting), diaphoresis, dizziness, double or

> blurred vision, decrease in both blood pressure and heart rate and pallor . . ."

Yet additional evidence that Heaton et al. disclosure is nonenabling for Applicants' novel technology is provided at page 203, right column, as follows. From "Study 3", involving intranasal administration of an unmodified, aqueous apomorphine formulation, the following report is provided:

> Two patients were administered apomorphine by intranasal spray and both experienced significant adverse effects (yawning, nausea, vomiting, dizziness, blurred vision, diaphoresis, pallor, mild hypotension, and bradycardia . . .. No further attempts were made to test this preparation or route of administration.

In their concluding discussion (page 205, left column), Heaton and coworkers explicitly state that "[u]nmodified apomorphine given orally or sublingually may be effective in producing erections but is associated with unacceptable adverse side effects."

In view of the foregoing facts and authority, the Heaton et al. reference cited by the Office clearly fails to anticipate or inherently disclose Applicants' invention as claimed herein. On the contrary, the express disclosure of the reference itself unambiguously establishes that the disclosure is nonenabling for the claimed aqueous apomorphine formulations that yield "enhanced nasal absorption . . . to produce a therapeutic result in said subject" (in accordance with the recited pharmacokinetic values) "without unacceptable adverse side effects in said subject." The teachings of Heaton et al. clearly preclude a finding that each and every element and limitation of Applicants' claimed invention is either inherently disclosed or enabled by the cited reference.

On this basis, the rejection of claims 21-32 and 39 under 35 U.S.C. 102(b) as allegedly anticipated by Heaton et al. is respectfully submitted to be overcome.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance and an action to that end is urged. If the Examiner believes a telephone conference would aid in the prosecution of this case in any way, please call the undersigned at (425) 455-5575.

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